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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/380,200	01/30/95	BIRNSTIEL M	0652.1080001

HM12/0524
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EXAMINER	
NOLAN, P	
ART UNIT	**PAPER NUMBER**
1644	42
DATE MAILED:	05/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/380,200	Applicant(s) Birnstiel et al.
	Examiner Nolan	Group Art Unit 1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 3/9/00.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-40 is/are pending in the application.

Of the above claim(s) 3-7, 11-12, 15-16, 21-27, 30-35, 37 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, 8, 13, 14, 17-20, 28, 36, 38-40 is/are rejected.

☒ Claim(s) 9-10, 29 is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Part III DETAILED ACTION

1. This application is a continuation of 07/946,498.

2. Claims 1-40 are pending.

3. Applicant's election without traverse of Species D from Group I, monoclonal antibody to CD3, Species C from Group II, polylysine, and Species A from Group III, virus inhibiting ribozyme in Paper No. 41 is acknowledged.

The claims which read upon the elected species are 1, 2, 8-10, 13-14, 17-20, 28, 29, 36 and 38-40. Claim 6 has not been examined as reading upon the elected species because CD3 is not a tumor associated antigen.

Accordingly, claims 3-7, 11-12, 15-16, 21-27, 30-35 and 37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 2, 8, 13, 14, 17-20, 28, 36, 38-40 are rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No.

5,166,320, of record, in view of U.S. Patent 5,144,019 and U.S. Patent 5,428,132.

The `320 patent teaches the use of antibody-polylysine-polynucleotide conjugate for introducing polynucleotides into cells via receptor mediated endocytosis, wherein said antibody is directly coupled (i.e. disulfide bonds) to polylysine. The `320 patent also teaches that use of the antibody-polylysine-polynucleotide conjugate is advantageous over liposome delivery of polynucleotides because it is difficult to control the leakage of contents of the liposome and to direct cell specificity. Lastly, the `320 patent teaches that by noncovalently conjugating the polynucleotides to polylysine it allows for the polynucleotides to not be damaged or altered so successful in vivo endocytosis and expression of said polynucleotide can occur.

The claimed invention differs from the prior art teachings by the recitations of using a virus inhibiting ribozyme as the polynucleotide and monoclonal anti-CD3 antibody as the targeting ligand for T cells. However, the `019 patent teaches a virus inhibiting ribozyme and use of a liposome to target said ribozyme to CD4+ (i.e. T cells) in vivo. The `132 patent teaches the use of anti-CD3 monoclonal antibodies conjugated to DNA to deliver said DNA to T cells in vivo.

One of ordinary skill in the art at the time the invention was made would have been motivated to use the antibody-polylysine-polynucleotide conjugate taught by the `320 patent and substitute an HIV virus inhibiting ribozyme taught by the '019 patent and monoclonal anti-CD3 antibody taught by the '132 patent because the polycation delivery method is advantageous over the liposome delivery method taught by the '019 patent because in liposomes it is difficult to control the leakage of contents of the liposome and to direct cell specificity and the use of non-covalent linkage of polynucleotides is advantageous over covalent linkage of DNA taught by the `132 patent because noncovalently conjugating the polynucleotides to polylysine allows for the polynucleotides to not be damaged or altered so successful in vivo endocytosis and expression of said polynucleotide can occur. Lastly the use of anti-CD3 monoclonal antibodies to target T cells would have been obvious because all HIV infected T cells are CD3+ and specifically targeting the virus inhibiting ribozyme for cell specificity is taught by the '320 patent as use for the antibody-polylysine-polynucleotide conjugate. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

5. Claims 9-10 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in

independent form including all of the limitations of the base claim and any intervening claims.

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan, Ph.D.
Patent Examiner, Group 1640
May 22, 2000

Christina Chan
CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640